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Filing date:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92058417
Party	Defendant Kythera Biopharmaceuticals, Inc.
Correspondence Address	KYTHERA BIOPHARMACEUTICALS INC 27200 WEST AGOURA ROAD , SUITE 200 CALABASAS, CA 91301 UNITED STATES
Submission	Motion to Suspend for Civil Action
Filer's Name	John J. Dabney
Filer's e-mail	jdabney@mwe.com, mhallerman@mwe.com, dciplit@mwe.com, kbukrinsky@mwe.com
Signature	/s/ John J. Dabney
Date	01/23/2014
Attachments	Corrected Kythera 92058417.pdf(13555 bytes ) Kythera v. Lithera Complaint.pdf(802739 bytes ) Lithera's MTD.pdf(71012 bytes )

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Lithera, Inc.	)		
Petitioner,	)		
v.	)	Cancellation No.	92058417
Kythera Biopharmaceuticals, Inc.,	)		
Registrant.	)		

#### REGISTRANT'S CORRECTED MOTION TO SUSPEND

Registrant Kythera Biopharmaceuticals, Inc. ("Kythera") hereby moves for an Order suspending this Cancellation pending the disposition of Civil Action No. CV13-6338 RSWL, *Kythera Biopharmaceuticals, Inc. v. Lithera, Inc.*, in the U.S. District Court for the Central District of California. This Corrected Motion corrects a typo in the signature block of Registrant's January 21, 2014 motion, but is otherwise identical.

In the California action, Registrant filed a complaint alleging that Petitioner's use of LITHERA for pharmaceutical preparations constitutes trademark infringement of Registrant's KYTHERA mark, which Registrant has used in connection with its pharmaceutical goods and services since early 2006. Petitioner filed a motion to dismiss alleging the identical grounds as those Petitioner alleged in its Petition for Cancellation. Copies of Registrant's complaint and Petitioner's motion to dismiss are attached. Registrant requests that this Cancellation be suspended because the pending civil action has a direct bearing on this proceeding.

Dated: January 23, 2014 Kythera Biopharmaceuticals, Inc.

Katie Bukrinsky McDermott Will & Emery LLP 500 North Capitol Street Washington, DC 20001 Attorneys for Registrant

### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of this paper has been served upon all parties, at their address of record, by first class mail, on January 23, 2014.

Respectfully submitted,

/John J. Dabney/\_\_\_\_

John J. Dabney Attorney for Registrant

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## STATEMENT OF THE CASE

This is an action for trademark infringement, false designation of 1. origin, unfair competition, trade name infringement and trademark cancellation. Since at least as early as 2006, Kythera has continuously used the mark and trade name KYTHERA in connection with the advertising and promotion of pharmaceutical research and development services and related goods and services. Kythera's lead product candidate is an injectable drug (ATX-101), which is currently in Phase III clinical development for the aesthetic reduction of localized subcutaneous fat deposits in humans. Kythera owns an incontestable federal trademark registration for KYTHERA for, among other things, the development of pharmaceutical preparations and medicines. Despite Kythera's registration, Defendant commenced use and secured registration of the confusingly similar mark and trade name, LITHERA, for pharmaceutical preparations. Lithera is also in the process of developing an injectable drug (LIPO-202), which is currently in Phase II clinical development for the aesthetic reduction of localized subcutaneous fat deposits in humans.

## **PARTIES**

2. Kythera is a Delaware corporation with its principal place of business in California.

3. Defendant is a Delaware corporation with its principal place of business in California.

## **JURISDICTION AND VENUE**

- 4. Kythera's claims arise under the trademark laws of the United States of America, 15 U.S.C. § 1051 *et seq.*, and the laws of the State of California. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, and 1367, and 15 U.S.C. § 1121. This Court has supplemental jurisdiction over the claims arising under the laws of the State of California under 28 U.S.C. § 1367(a), because those claims are so related to the federal claims that they are part of the same case or controversy and derive from a common nucleus of operative fact.
- 5. This Court has personal jurisdiction over Defendant. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims herein occurred in this judicial district.

## FACTUAL BACKGROUND

- 6. Founded in 2005, Kythera is a biopharmaceutical company dedicated to the research and development of pharmaceuticals used in aesthetic medicine, including in particular, pharmaceuticals to reduce human body fat.
- 7. Since at least as early as 2006, Kythera has continuously used the mark and trade name KYTHERA for its pharmaceutical research and development services and related goods and services, including its lead product candidate (ATX-101) which is designed to reduce human body fat.

Complaint

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- 8. Kythera owns common law marks and trade names for KYTHERA for a variety of goods and services, including medical research and development in connection with pharmaceutical preparations and biotechnology; pharmaceutical drug development services and product evaluation, including conducting clinical trials, testing and inspection of pharmaceuticals, and related goods and services.
  - Kythera owns a federal trademark registration for KYTHERA for:

    Chemical research; Chemical, biochemical, biological and bacteriological research and analysis; Conducting early evaluations in the field of new pharmaceuticals; Development and test of chemical production methods; Development of new technology for others in the field of biotechnology;

    Development of pharmaceutical preparations and medicines;

    Medical and scientific research in the field of biotechnology;

    medical and scientific research, namely, conducting clinical trials; Pharmaceutical drug development services;

    Pharmaceutical product evaluation; Pharmaceutical research and development; Pharmaceutical research services; Research on the subject of pharmaceuticals; Testing, inspection or research of pharmaceuticals, cosmetics or foodstuff.
- U.S. Reg. No. 3357920 (registered Dec. 18, 2007) (attached as Exhibit A).
- 10. Kythera's registration for KYTHERA (U.S. Reg. No. 3357920) has achieved "incontestable" status under the Lanham Act, meaning that it is "conclusive evidence" of Kythera's "ownership" of this mark, of the registration of this mark, the "validity" of this mark," and of Kythera's "exclusive right" to use the KYTHERA mark in commerce for the goods and services specified in the registration. *See* 15 U.S.C. §§ 1065, 1115(b).
  - 11. Kythera also owns a federal trademark registration for KYTHERA for:

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Research and development of pharmaceutical preparations and aesthetic preparations; medical and scientific research information in the fields of pharmaceutical preparations, aesthetic preparations and clinical trials; and providing a website featuring information about investigational pharmaceutical preparations and aesthetic preparations.

- U.S. Reg. No. 4012388 (registered Aug. 16, 2011) (attached as Exhibit B).
- 12. Kythera has invested considerable resources to advertise and promote its goods and services under its KYTHERA marks and trade names.
- Kythera's KYTHERA marks and trade names are inherently 13. distinctive and have acquired secondary meaning in the marketplace as designating goods and services emanating exclusively from Kythera.
- 14. Long after Kythera's first use of its KYTHERA marks and trade names, Defendant filed an intent-to-use application in the U.S. Patent and Trademark Office ("USPTO") for LITHERA for "pharmaceutical preparations for reducing the size and appearance of adipose deposits in a body." Defendant advertises its good and services at lithera.com.
- 15. Defendant's trademark application alleged a date of first use of LITHERA in commerce of September 2011. The USPTO registered Defendant's LITHERA mark, Reg. No. 4067542 on December 6, 2011.
- Defendant's LITHERA mark and trade name is similar to Kythera's 16. KYTHERA marks and trade names in sight, sound, meaning and overall visual impression.

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- 17. Defendant's goods and services in connection with which it uses the mark and trade name LITHERA are similar and related to, and overlap with the goods and services with which Kythera uses its KYTHERA marks and trade names.
- The parties' respective goods which will be sold in connection with 18. their respective marks will be marketed through the same channels of trade, advertised in the same mediums, target the same customers and serve similar functions.
- Defendant's use of LITHERA has caused confusion, mistake and/or 19. deception in the marketplace, including among sophisticated individuals in the field of pharmaceuticals and in the press. Attached as Exhibit C is a copy of a "Letter to the Editor" published in the March 2013 edition of the "Aesthetic Surgery Journal" in which the authors confuse the KYTHERA and LITHERA products.
- The parties' goods and services are discussed and presented under the 20. KYTHERA and LITHERA marks and names in the same publications, including investor publications and at the same conferences. At the AAD annual conference in Miami, Florida earlier this year, a presenter used the name KYTHERA when referring to LITHERA and vice versa.
- Defendant's use of LITHERA is likely to cause confusion, mistake, 21. and/or deception as to the affiliation, connection, or association of Defendant with Kythera and as to whether Kythera approves, sponsors, or endorses Defendant's goods and services.

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22.	Defendant's wrongful conduct has caused Kythera to lose control over
the reputation	on associated with Kythera's KYTHERA marks and names.

- 23. Kythera demanded that Defendant cease and desist all use of LITHERA and similar names and marks, but Defendant refuses to do so.
- 24. Kythera has suffered damages and Defendant has obtained profits or been unjustly enriched as a result of Defendants' wrongful conduct.

## **COUNT I**

# TRADEMARK INFRINGEMENT, UNFAIR COMPETITION, AND FALSE DESIGNATION OF ORIGIN UNDER THE LANHAM ACT (15 U.S.C. § 1114)

- 25. Kythera re-alleges and incorporates the allegations in the paragraphs above as if fully set forth herein.
- 26. Kythera owns federally registered trademarks for KYTHERA for, among other things, research and development of pharmaceutical preparations. *See, e.g.*, U.S. Reg. No. 3357920.
- 27. Defendant's use of LITHERA constitutes trademark infringement, unfair competition, and false designation of origin because such use is likely to cause confusion, mistake, and deception as to the affiliation, connection, association, origin, sponsorship, or approval of Defendant's goods or services.
- 28. Defendant's wrongful conduct has caused Kythera to lose control over the reputation and goodwill associated with Kythera's KYTHERA marks.

29.	Defendant's wrongful conduct is causing Kythera irreparable harm and
damages.	Defendant has been unjustly enriched by its unlawful conduct.

30. Unless Defendant is enjoined from its wrongful conduct, Kythera will continue to suffer irreparable injury and harm, for which Kythera has no adequate remedy at law.

### **COUNT II**

# TRADEMARK INFRINGEMENT, UNFAIR COMPETITION, FALSE DESIGNATION OF ORIGIN AND TRADE NAME INFRINGEMENT UNDER THE LANHAM ACT (15 U.S.C. § 1125)

- 31. Kythera re-alleges and incorporates the allegations in the paragraphs above as if fully set forth herein.
- 32. Kythera owns common law marks and trade names for KYTHERA for, among other things, research and development of pharmaceutical preparations.
- 33. Defendant's unauthorized use of LITHERA constitutes trademark infringement, unfair competition, and false designation of origin because such use is likely to cause confusion, mistake, and false designation of origin because such conduct is likely to cause confusion, mistake, and deception as to the affiliation, connection, association, origin, sponsorship, or approval of Defendant's goods or services.

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	34.	Defendant's wrongful conduct has caused Kythera to lose control over
the re	eputatio	on and goodwill associated with Kythera's KYTHERA marks and
name	s.	

- 35. Defendant's wrongful conduct is causing Kythera irreparable harm and damages. Defendant has been unjustly enriched by its unlawful conduct.
- 36. Unless Defendant is enjoined from its wrongful conduct, Kythera will continue to suffer irreparable injury and harm, for which Kythera has no adequate remedy at law.

### **COUNT III**

## TRADEMARK CANCELLATION (15 U.S.C. §§ 1052(d), 1119)

- 37. Kythera re-alleges and incorporates the allegations in the paragraphs above as if fully set forth herein.
- 38. Defendant's U.S. Trademark Registration No. 4067542 for LITHERA is likely to cause confusion, deception and/or mistake with respect to Kythera's KYTHERA marks and names. *See* 15 U.S.C. §§ 1052(d), 1119.
- 39. Kythera is likely to be damaged by Defendant's maintenance of U.S. Trademark Registration No. 4067542.

## COUNT IV

TRADEMARK INFRINGEMENT, UNFAIR COMPETITION, FALSE DESIGNATION OF ORIGIN AND TRADE NAME INFRINGEMENT UNDER CALIFORNIA LAW

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- Kythera re-alleges and incorporates the allegations in the paragraphs 40. above as if fully set forth herein.
- Defendant's use of LITHERA constitutes trademark infringement, 41. unfair competition, false designation of origin, and trade name infringement in violation of California common law and California Business & Professions Code § 17200 et seq., because it is likely to cause confusion, mistake, or deception as to source, origin, affiliation, connection, or association.
- Defendant's wrongful conduct has caused Kythera to lose control over 42. the reputation and goodwill associated with Kythera's KYTHERA marks and names.
- Kythera has suffered damages and Defendant has obtained profits or 43. been unjustly enriched as a result of Defendants' wrongful conduct.
- 44. Defendant's acts irreparably injure Kythera's business, reputation, and goodwill. Unless Defendant is enjoined from its wrongful conduct, Kythera will continue to suffer irreparable injury and harm, for which Kythera has no adequate remedy at law.

## PRAYER FOR RELIEF

WHEREFORE, based on the foregoing allegations, Kythera prays for judgment against Defendant as follows:

That this Court enter judgment in favor of Kythera and against 1. Defendant on all claims for relief alleged herein;

Complaint - 10 -

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2. That this Court issue a permanent injunction:

- a. enjoining Defendant, its employees, owners, agents, officers, directors, attorneys, representatives, affiliates, subsidiaries, successors, and assigns, and all those in active concert or participation with them or having knowledge of the causes of action, including Defendant's dealers, from using the mark or trade name LITHERA, alone or in combination with any other word(s), term(s), designation(s), mark(s) and/or design(s) as well as all similar marks and names;
- b. requiring Defendant to deliver up for destruction all literature, signs, billboards, labels, prints, packages, wrappers, containers, advertising materials, stationery, and other items in their possession, custody or control that use LITHERA pursuant to 15 U.S.C. § 1118;
- c. requiring Defendant to transfer its domain name **lithera.com** and all similar names to Kythera;
- d. requiring the United States Patent and Trademark Office to cancel Defendant's U.S. Trademark Registration No. 4067542 for LITHERA, 15 U.S.C. § 1119; and
- e. requiring Defendant to file with the Court and serve on Kythera, within thirty (30) days after entry of an injunction, a report in

writing under oath setting forth in detail the manner in which

Defendant has complied with the Court's injunction.

- 3. That this Court grant monetary relief in the form of:
  - a. an accounting to Kythera of any and all profits derived by
     Defendant from the acts complained of herein;
  - b. Kythera's general, special, and/or actual damages, along with any other damages allowable under 15 U.S.C. § 1117 and any other applicable statute or at common law, according to proof at trial;
  - c. a trebling of the damages awarded to Kythera and an enhanced award of Defendant's profits to Kythera, as provided for by 15 U.S.C. § 1117(a);
  - d. Kythera's costs and reasonable attorneys' fees pursuant to 15
     U.S.C. § 1117(a) and California common and statutory law; and
  - e. punitive or exemplary damages, as permitted by California law.
- 4. That this Court grant Kythera such other and further relief, in law or in equity, as it should deem just and proper.

## **JURY DEMAND**

Kythera respectfully demands a trial by jury on all claims and issues so triable.

1	Dated: August 29, 2013	Respectfully submitted,
2		McDERMOTT WILL & EMERY LLP
3		
5		By:
6		Philip On ) MCDERMOTT WILL & EMERY LLP
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8		275 Middlefield Road, Suite 100 Menlo Park, CA 94025 Telephone: (650) 815-7400 Facsimile: (650) 815-7401 pou@mwe.com
9		John J. Dabney
10 11		John J. Dabney Mary D. Hallerman MCDERMOTT WILL & EMERY
12		
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14		jdabney@mwe.com mhallerman@mwe.com
15		Attorneys for Plaintiff KYTHERA
16		KYTHERA BIOPHARMACEUTICALS, INC.
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MCDERMOTT WILL & EMERY LLP
ATTORNEYS ATLAW
WASHINGTON

# Exhibit A

Int. Cl.: 42

Prior U.S. Cls.: 100 and 101

United States Patent and Trademark Office

Reg. No. 3,357,920

Trademark Office Registered Dec. 18, 2007

#### SERVICE MARK PRINCIPAL REGISTER

## **KYTHERA**

AESTHERX INC (DELAWARE CORPORATION) 6303 OWENSMOUTH AVE WOODLAND HILLS, CA 91367

FOR: CHEMICAL RESEARCH; CHEMICAL, BIO-CHEMICAL, BIOLOGICAL AND BACTERIOLOGICAL RESEARCH AND ANALYSIS; CONDUCTING EARLY EVALUATIONS IN THE FIELD OF NEW PHARMACEUTICALS; DEVELOPMENT AND TEST OF CHEMICAL PRODUCTION METHODS; DEVELOPMENT OF NEW TECHNOLOGY FOR OTHERS IN THE FIELD OF BIOTECHNOLOGY; DEVELOPMENT OF PHARMACEUTICAL PREPARATIONS AND MEDICINES; MEDICAL AND SCIENTIFIC RESEARCH IN THE FIELD OF BIOTECHNOLOGY; MEDICAL AND SCIENTIFIC RESEARCH, NAMELY, CONDUCTING CLINICAL TRIALS; PHARMACEUTICAL DRUG DEVELOPMENT SERVICES;

PHARMACEUTICAL PRODUCT EVALUATION; PHARMACEUTICAL RESEARCH AND DEVELOPMENT; PHARMACEUTICAL RESEARCH SERVICES; RESEARCH ON THE SUBJECT OF PHARMACEUTICALS; TESTING, INSPECTION OR RESEARCH OF PHARMACEUTICALS, COSMETICS OR FOODSTUFF, IN CLASS 42 (U.S. CLS. 100 AND 101).

FIRST USE 7-24-2006; IN COMMERCE 7-24-2006.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PARTICULAR FONT, STYLE, SIZE, OR COLOR.

SN 78-909,668, FILED 6-15-2006.

MATTHEW PAPPAS, EXAMINING ATTORNEY

# Exhibit B

## United States of America Muitod States Aatont and Arahemark Office United States Patent and Trademark Office

# KYTHERA

Reg. No. 4,012,388

KYTHERA BIOPHARMACEUTICALS, INC. (DELAWARE CORPORATION) 27200 WEST AGOURA ROAD, SUITE 200

Registered Aug. 16, 2011 CALABASAS, CA 91301

Int. Cl.: 42

SERVICE MARK

PRINCIPAL REGISTER

FOR: RESEARCH AND DEVELOPMENT OF PHARMACEUTICAL PREPARATIONS AND AESTHETIC PREPARATIONS; MEDICAL AND SCIENTIFIC RESEARCH INFORMATION IN THE FIELDS OF PHARMACEUTICAL PREPARATIONS, AESTHETIC PREPARATIONS AND CLINICAL TRIALS; AND PROVIDING A WEBSITE FEATURING INFORMATION ABOUT INVESTIGATIONAL PHARMACEUTICAL PREPARATIONS AND AESTHETIC PREPARATIONS, IN CLASS 42 (U.S. CLS. 100 AND 101).

FIRST USE 0-0-2006; IN COMMERCE 0-0-2006.

THE MARK CONSISTS OF STANDARD CHARACTERS WITHOUT CLAIM TO ANY PAR-TICULAR FONT, STYLE, SIZE, OR COLOR.

OWNER OF U.S. REG. NO. 3,357,920.

SER. NO. 85-225,218, FILED 1-25-2011.

JORDAN BAKER, EXAMINING ATTORNEY



Director of the United States Patent and Trademark Office

## REQUIREMENTS TO MAINTAIN YOUR FEDERAL TRADEMARK REGISTRATION

WARNING: YOUR REGISTRATION WILL BE CANCELLED IF YOU DO NOT FILE THE DOCUMENTS BELOW DURING THE SPECIFIED TIME PERIODS.

Requirements in the First Ten Years\*
What and When to File:

First Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) between the 5th and 6th years after the registration date. See 15 U.S.C. §§1058, 1141k. If the declaration is accepted, the registration will continue in force for the remainder of the ten-year period, calculated from the registration date, unless cancelled by an order of the Commissioner for Trademarks or a federal court.

Second Filing Deadline: You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between the 9th and 10th years after the registration date.\*

See 15 U.S.C. §1059.

## Requirements in Successive Ten-Year Periods\* What and When to File:

You must file a Declaration of Use (or Excusable Nonuse) and an Application for Renewal between every 9th and 10th-year period, calculated from the registration date.\*

#### Grace Period Filings\*

The above documents will be accepted as timely if filed within six months after the deadlines listed above with the payment of an additional fee.

The United States Patent and Trademark Office (USPTO) will NOT send you any future notice or reminder of these filing requirements.

\*ATTENTION MADRID PROTOCOL REGISTRANTS: The holder of an international registration with an extension of protection to the United States under the Madrid Protocol must timely file the Declarations of Use (or Excusable Nonuse) referenced above directly with the USPTO. The time periods for filing are based on the U.S. registration date (not the international registration date). The deadlines and grace periods for the Declarations of Use (or Excusable Nonuse) are identical to those for nationally issued registrations. See 15 U.S.C. §§1058, 1141k. However, owners of international registrations do not file renewal applications at the USPTO. Instead, the holder must file a renewal of the underlying international registration at the International Bureau of the World Intellectual Property Organization, under Article 7 of the Madrid Protocol, before the expiration of each ten-year term of protection, calculated from the date of the international registration. See 15 U.S.C. §1141j. For more information and renewal forms for the international registration, see http://www.wipo.int/madrid/en/.

NOTE: Fees and requirements for maintaining registrations are subject to change. Please check the USPTO website for further information. With the exception of renewal applications for registered extensions of protection, you can file the registration maintenance documents referenced above online at http://www.uspto.gov.

# Exhibit C





A Future for Injection Lipolysis?
Brent Tanner, Tony Barabas, David Crook and Colin Link
Aesthetic Surgery Journal 2013 33: 456 DOI: 10.1177/1090820X13477104

The online version of this article can be found at: http://aes.sagepub.com/content/33/3/456

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>> Version of Record - Mar 20, 2013

What is This?



#### Letter to the Editor

## A Future for Injection Lipolysis?

Aesthetic Surgery Journal 33(3) 456–457 © 2013 The American Society for Aesthetic Plastic Surgery, Inc. Reprints and permission: http://www.sagepub.com/journalsPermissions.nav

Brent Tanner, MA, FRCS; Tony Barabas, BM, BSc, MRCS, FRCS (plast); David Crook, PhD; and Colin Link, MBBS, BSc

www.aestheticsurgeryjournal.com

Nearly a decade has passed since we first began our audit of clinical outcomes using multiple subcutaneous injections of the lipodissolve agent Lipostabil N (Sanofi-Aventis, Frankfurt, Germany) to reduce adipose deposits in the abdomen and other areas. That lipodissolve agent contained phosphatidylcholine (PC) and deoxycholate (DC) as active ingredients. These derivatives of soya bean and bile extracts respectively had regulatory approval for certain applications, but neither had been formally approved for subcutaneous injection. However, this mixture gained early support as an off-label, minimally invasive alternative to traditional lipoplasty techniques.<sup>2</sup>

By 2006, regulatory agencies such as the US Food and Drug Administration (FDA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) had restricted the import of Lipostabil N for cosmetic applications. They were concerned about the lack of clinical testing and the apparent misrepresentation of benefit by some weight loss clinics.<sup>3</sup>

PC-DC subcutaneous injections are not target specific. Instead, this detergent-like mixture kills any tissue into which it is injected. Late consequences of injecting a DC formula into fat can include necrobiosis of the adjacent reticular dermis, with death of adnexal glands, blood vessels, and nerves in the deep dermal layer. When used in excess, skin contour irregularities have been reported, which are essentially a result of the product working too well. For this reason, our own treatment policy is to use a small amount of the product in an initial treatment session, followed by repeat treatments as required. With this treatment protocol, our patients experience none of the theoretical complications documented elsewhere.

Almost all of our patients experience temporary and minor side effects after treatment, including reddening, swelling, and bruising at the injection sites. These symptoms can last up to a week. In our audit, in which we analyzed over 100 patient responses, subjective ratings showed a bimodal distribution, with over 75% being very satisfied and less than 25% reporting no visible improvement. There was a statistically significant (P < .05 by  $\chi^2$  test) positive outcome in all body areas treated, independent of body mass index.

Our patient satisfaction level was over 85% when lipodissolve was used to treat excess orbital fat compartments, neck, submental, and jowl fat. In these applications, the treatment cost and downtime compare favorably to the surgical alternative. In the majority of cases, the improvements began to show after the swelling had resolved, with the optimal reduction of fat evident after about 6 weeks.

The advantages of PC-DC injections include costeffectiveness and the lack of need for any specialized
equipment. However, a caveat is that nonphysician injectors may not possess the anatomical knowledge and training to reduce the risk of complications. In the past decade,
many patients were treated in clinics staffed by nurses, but
the tide turned when the gravity of potential treatment
complications became known.

Now, there are companies investing in new lipodissolve products. Lithera (San Diego, California) offers Lipo 102, which contains only the DC component and is reportedly not associated with any risk of skin necrosis or loss of eccrine glands in the deep dermis. Kythera (Calabasas, California) is also conducting rigorous clinical trials of a lipodissolve product called ATX-101.5.6

As our own findings on lipodissolve injections were positive, we are convinced that this technology may have value for certain cosmetic and reconstructive applications. Therefore, we await the results of these trials with interest.

Editor's Note: Please see results from a Level 3 clinical trial entitled "Metabolic and Structural Effects of Phosphatidyl-choline and Deoxycholate Injections on Subcutaneous Fat: A Randomized, Controlled Trial" in this same issue.

Dr Tanner is a Consultant Plastic Surgeon at Spire Hospital, Tunbridge Wells, UK. Dr Barabas is a Plastic Surgery Registrar at Queen Victoria Hospital, East Grinstead, UK. Dr Crook is a Senior Research Fellow at the University of Brighton, Brighton, UK. Dr Link is a Senior House Officer at Guys Hospital, London, UK.



Tanner et al

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#### **Disclosures**

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

#### REFERENCES

- Tanner B. Phosphatidyl choline (PC): has it a role in reconstructive plastic surgery? Presented at the Winter Meeting of the British Association of Plastic, Reconstructive and Aesthetic Surgeons; December 2006; London, UK.
- Duncan D, Hasengschwandtner F. Lipodissolve for subcutaneous fat reduction and skin retraction. *Aesthetic* Surg J. 2005;25:530-543.

- 3. Atiyeh BS, Ibrahim AE, Dibo SA. Cosmetic mesotherapy: between scientific evidence, science fiction, and lucrative business. *Aesthetic Plast Surg.* 2008;32:842-849.
- Duncan D, Palmer M, Fat reduction using phosphatidylcholine/sodium deoxycholate injections: standard of practice. Aesthetic Plast Surg. 2008;32:858-872.
- Goodman G. Reduction of submental fat with ATX-101: a pooled analysis of two international multicenter, doubleblind, randomized, placebo-controlled studies. J Am Acad Dermatol. 2012;66(suppl 1):AB11.
- http://clinicaltrials.gov/ct2/results?term = ATX-101& Search = Search/. Accessed October 26, 2012.

## UNITED STATES DISTRICT COURT CENTRAL DISTRICT OF CALIFORNIA

## NOTICE OF ASSIGNMENT TO UNITED STATES JUDGES

	en assigned to District Judge	Ronald S.V	V. Lew	and the assigned
Magistrate Judge is	Suzanne H. Segal	*		
The cas	e number on all documents fil	ed with the Court sho	ould read as foll	lows:
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All discovery rela	ated motions should be noticed	1 on the calendar of th	ie Magistrate Ji	udge.
·		Clerk, U. S. I	District Court	
August 29, 20 Date	13	By <u>J.Prado</u> Deputy C	lerk	
	NOTICE T	O COUNSEL		
A copy of this notice mus filed, a copy of this notice	t be served with the summons a must be served on all plaintiffs	nd complaint on all de ).	efendants (if a 1	removal action is
Subsequent documents	must be filed at the following	location:		
Western Division 312 N. Spring Stree Los Angeles, CA 90		th St., Ste 1053	Eastern Divisi 3470 Twelfth Riverside, CA	Street, Room 134
Failure to file at the pro	per location will result in you	r documents being re	eturned to you	• •
7-18 (08/13)	NOTICE OF A SUCHMENT TO	INTER STATES WINGS		

AO 440 (Rev. 06/12) Summons in a Civil Action

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## ORIGINAL

## UNITED STATES DISTRICT COURT

for the

Central 1	District of California
	Sister of Carroyaga
Kythera Biopharmaceuticals, Inc.	)
	į
Plaintiff(s)	CV13- 6338D SALLES
v.	Civil Action No. 6338 RSWL (SS.)
Lithera, Inc.	ý
	)
Defendant(s)	
	IN A CIVIL ACTION
To: (Defendant's name and address) Lithera, Inc. 9191 Towne Centre Dri	VA
Suite 400 San Diego, CA 92122	••
A lawsuit has been filed against you.	
P. 12 (a)(2) or (3) — you must serve on the plaintiff an a the Federal Rules of Civil Procedure. The answer or mowhose name and address are: Philip Ou	a you (not counting the day you received it) — or 60 days if you ficer or employee of the United States described in Fed. R. Civ. answer to the attached complaint or a motion under Rule 12 of the served on the plaintiff or plaintiff's attorney,
McDermott Will & Emery 275 Middlefield Road	LLP
Suite 100 Menlo Park, CA 94025	•
If you fail to respond, judgment by default will be You also must file your answer or motion with the court.	be entered against you for the relief demanded in the complaint.
	CLERK OF COURT
AUG 2 9 2013	
Date:	
	Signature of the A Deputy Clerk
	\ /

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No.

### PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (1))

as r	eceived by me on (date)	·         •	***************************************	
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	☐ I personally served t	he summons on the individual a	it (place)	
			on (date)	; or
	☐ I left the summons a	t the individual's residence or u	sual place of abode with (name)	
			of suitable age and discretion who	resides there.
	On (date)		be individual's last known address;	
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Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action



## UNITED STATES DISTRICT COURT

for the

Central District of California

Kythera Biopharmaceuti	cals, Inc.	)	
		(PV47	/ ** ** A
Plaintiff(s)		OVL)	6338 RSWL(JSX)
v.	•	) Civil Action No.	, , ,
Lithera, Inc.		)	
		)	
Defendant(s)		ý	
Defendant(s)		)	
	SUMMONS IN A	A CIVIL ACTION	
To: (Defendant's name and address) Lith			
	11 Towne Centre Drive te 400		

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: Philip Ou

McDermott Will & Emery LLP 275 Middlefield Road Suite 100 Menlo Park, CA 94025

San Diego, CA 92122

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

AUG 2 9 2013

CLERK OF COURT

JULIE PRADO

Signature of Clerk or Deputy Clerk

ΑQ	440	(Rev.	06/12)	Summons	in a	Civil	Action	(Page 2
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Civil Action No.

### PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (1))

This summons for a	name of individual and title, if any)		166
was received by me on (date,			
☐ I personally serve	ed the summons on the individual	at (place)	
		on (date)	; or
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	, a perso	n of suitable age and discretion who the individual's last known address;	resides there,
☐ I served the summ	nons on (name of individual)  accept service of process on beha		, who i
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☐ I returned the sum	mons unexecuted because	On (date)	; or
Other (specify):			; or
My fees are \$	for travel and \$	for services, for a total of S	0.00
I declare under penalt	y of perjury that this information i	S true.	
te:			
	-	Server's signature	
		Printed name and title	
		Server's address	

## UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA

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CV-71 (02/13)

CIVIL COVER SHEET

Page 1 of 2

## UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA CIVIL COVER SHEET

VIII(a). IDENTICAL	CASES: Has th	s action been previously filed in this coul	rt and dismissed, remanded or closed?	X NO		YES
If yes, list case nur	mber(s):					
VIII(b). RELATED CA	SES: Have any	cases been previously filed in this court	that are related to the present case?	⊠ NO		YES
If yes, list case nun	mber(s):					
Civil cases are deemed	d related if a pre	riously filed case and the present case:				ATTACA TO A TO A TO A TO A TO A TO A TO
(Check all boxes that ap	oply) A. Ari	se from the same or closely related transaction	is, happenings, or events; or			
		for determination of the same or substantially		ır		
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IX. VENUE: (When com		ing information, use an additional sheet if nec				
(a) List the County in th plaintiff resides.	is District; Califo	ornia County outside of this District; State	if other than California; or Foreign Coun	try, in which <b>E</b>	<b>ACH</b> nar	ned
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861	HIA	Substantive Statement of Cause of Action  All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))				
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)				
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; pl all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))				led; plu
863	DIWW	All claims filed for widows or widowers insu amended. (42 U.S.C. 405 (g))	rance benefits based on disability under Title	2 of the Social Se	curity Ac	t, as
864	SSID	All claims for supplemental security income amended.	payments based upon disability filed under T	tle 16 of the Soc	ial Securi	ty Act, a
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))				
/-71 (02/13)		CIVIL COVER SHEET		Page 2	of 2	***************************************

1 2 3 4 5 6 7 8	Benjamin A. Katzenellenbogen (SBN Ben.katzenellenbogen@knobbe.com Emily K. Sauter (SBN 265,679) Emily.sauter@knobbe.com KNOBBE, MARTENS, OLSON & E 2040 Main Street, Fourteenth Floor Irvine, CA 92614 Phone: (949) 760-0404 Facsimile: (949) 760-9502  Attorneys for Defendant LITHERA, INC.					
9	IN THE UNITED ST	TATES DISTRIC	T COURT			
10	FOR THE CENTRAL	DISTRICT OF C	ALIFORNIA			
11	WESTE	ERN DIVISION				
12	KYTHERA	) Civil Action No	o. CV13-6338 RSWL (SSx)			
13	BIOPHARMACEUTICALS, INC.,	) Hon. Ronald S.W. Lew				
14	Plaintiff,	) ) MEMORAND	UM OF POINTS AND			
15	V.	) AUTHORITIE ) LYTHERA, IN	S IN SUPPORT OF IC.'S MOTION TO			
16	LITHERA, INC.	) DISMISS THE	COMPLAINT			
17	Defendant.	) Date: ) Time: Location:	January 7, 2014 10:00 a.m. Courtroom 21			
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### 1 TABLE OF CONTENTS 2 Page No. 3 I. 4 II. 5 III. 6 7 The Court may consider Plaintiff's Trademark Office A. 8 9 The Complaint, Trademark Office records, and SEC В. filings show that both parties are clinical-stage 10 pharmaceutical companies who do not provide 11 services to others or offer any commercially available products......4 12 Plaintiff has alleged facts that establish there is no C. 13 14 Plaintiff has not acquired any service mark rights D. 15 because its research services are solely performed for 16 17 E. As a practical matter, Plaintiff's claims are premature because the Court could not even conduct the 18 likelihood of confusion analysis .......9 19 IV. 20 21 22 23 24 25 26 27 28

### TABLE OF <u>AUTHORITIES</u> Page No(s). AMF Inc. v. Sleekcraft Boats, Ashcroft v. Iqbal, Aycock Eng'g, Inc. v. Airflite, Inc., Bell Atl. Corp. v. Twombly, Brookfield Commc'ns, Inc. v. West Coast Entm't Corp., Chance v. Pac-Tel Teletrac, Inc., Daniels-Hall v. Nat'l Educ. Ass'n, Entrepeneur Media, Inc. v. Smith, GoTo.com, Inc. v. Walt Disney Co., In re Canadian Pacific Ltd., Mister Donut of Am., Inc. v. Mr. Donut, Inc., Playboy Enters., Inc. v. Netscape Commc'ns Corp., Plevy v. Haggerty,

**TABLE OF AUTHORITIES** (continued) Page No(s). Pollution Denim & Co. v. Pollution Clothing Co., Rearden LLC v. Rearden Commerce, Inc., U.S. v. Ritchie, OTHER AUTHORITIES 

Defendant Lithera, Inc. submits this Memorandum in support of its Motion to Dismiss the Complaint filed by Plaintiff Kythera Biopharmaceuticals, Inc.

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## I. INTRODUCTION

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Plaintiff's Complaint for trademark infringement and trademark cancellation should be dismissed for two reasons. First, Plaintiff does not allege any facts that could plausibly establish a likelihood of confusion. Second, the facts Plaintiff does allege establish that Plaintiff lacks any enforceable trademark rights in the asserted service marks.

Plaintiff and Defendant are both early stage pharmaceutical companies. They are both in the process of conducting clinical trials for their respective product candidates, and neither of them has any commercially available products. Neither offers to perform pharmaceutical research services for others. Since neither party sells any goods or service to customers, there are no goods or services over which any customers could be confused. In addition, as neither party has any customers, there are no customers who could possibly be confused. Thus, the allegation of likelihood of confusion, which forms the basis of Plaintiff's causes of action, is implausible.

In addition, Plaintiff lacks any enforceable rights in its alleged service marks. In order to develop protectable trademark rights in a service mark, a company must use a mark in connection with services performed for others. Plaintiff performs pharmaceutical research and development services solely for itself, for the purpose of developing its own products. Services performed solely for a company's own benefit do not give rise to enforceable trademark rights in a service mark.

As a practical matter, Plaintiff's allegations are simply premature. Even if the Court wanted to, there would be no way to apply the test for likelihood of confusion in a situation like this where neither party has any goods or services commercially available in a marketplace. Evaluating likelihood of confusion

involves considering factors that, at a minimum, require knowing information such as the names of the products, how those products are marketed and to whom they are marketed. Where, as here, there are no commercially available services or goods about which the public could be confused, and no relevant consuming public who could be confused, there can be no likelihood of confusion.

Accordingly, Plaintiff's allegations of likelihood of confusion and ownership of enforceable service marks are implausible, and do not state a claim for relief.

### II. LEGAL STANDARD

To survive a motion to dismiss, a complaint must allege facts sufficient "to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The complaint must "contain sufficient factual matter . . . to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint must allege more than just legal conclusions and "[t]hreadbare recitals of the elements of a cause of action." *Id*.

Courts are not required to accept as true "allegations that contradict exhibits attached to the Complaint or matters properly subject to judicial notice, or allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010).

## III. ARGUMENT

The complaint asserts four causes of action.<sup>1</sup> (Complaint, ¶¶ 25-44.) A courtesy copy of the complaint is attached as Exhibit 1 to the Declaration of Emily K. Sauter ("Sauter Dec."). Each claim relies on two assertions that are

Three causes of action allege essentially the same conduct (trademark and trade name infringement, unfair competition and false designation of origin) under two federal statues and California law. (Complaint (Ex. 1), ¶¶ 25-36, 40-44.) The fourth seeks cancellation of Defendant's Federal trademark registration for pharmaceutical preparations. (Complaint (Ex. 1), ¶¶ 37-39.)

contradicted by the allegations in the Complaint and other matters of public record. First, Plaintiff alleges that Defendant's actions are likely to cause confusion, deception and/or mistake with Plaintiff's marks and names. (*See* Complaint (Ex. 1), ¶¶ 27, 33, 38, 41 (alleging likelihood of confusion).) Second, Plaintiff alleges that it has protectable trademark rights in its service marks. (*See* Complaint (Ex. 1), ¶¶ 26, 32, 38, 40 (alleging protectable trademark rights) & Exs. A & B (attaching Plaintiff's service mark registrations).)

Neither of Plaintiff's assertions is plausible. As discussed in more detail below, the allegations in the Complaint establish that neither party offers any commercially available goods or services about which consumers could be confused. The allegations in the Complaint also demonstrate that Plaintiff has not used its marks in connection with providing services to others. Additional documents that are properly considered on this Motion, including the government records of Plaintiff's service mark applications and Plaintiff's SEC filings, further confirm the impossibility of Plaintiff's conclusory allegations. Accordingly, because Plaintiff's Complaint has not alleged a plausible claim for relief, the Court should grant Defendant's Motion to Dismiss.

# A. The Court may consider Plaintiff's Trademark Office records and SEC filings at the motion to dismiss stage

When considering a Rule 12(b)(6) motion to dismiss, a court can consider documents attached to the complaint, documents incorporated by reference in the complaint, and matters of which the Court may take judicial notice, without converting the motion to dismiss into a motion for summary judgment. *U.S. v. Ritchie*, 342 F.3d 903, 907-08 (9th Cir. 2003). Documents are incorporated by reference in a complaint when they are explicitly referred to the in the complaint or when they form the basis of the plaintiff's claim. *Id.* at 908.

Plaintiff's Complaint specifically attaches and refers to the records of Plaintiff's asserted federal service mark registrations, and those service mark

registrations are central to at least some of Plaintiff's claims of trademark infringement. Accordingly, the court may take judicial notice of the official Trademark Office records of the asserted registrations.

In addition, "[o]n a motion to dismiss, a court may take judicial notice of matters of public record outside the pleadings". *Plevy v. Haggerty*, 38 F. Supp. 2d 816, 821 (C.D. Cal. 1998). Records from the United States Patent and Trademark Office, as well as SEC filings, are matters of public record that courts may properly consider in resolving a motion to dismiss. *Pollution Denim & Co. v. Pollution Clothing Co.*, 547 F. Supp. 2d 1132, n.11 (C.D. Cal. 2007) (taking judicial notice of facts from trademark records maintained by the United States Patent and Trademark Office); *Plevy*, 38 F. Supp. 2d at 821 (finding that, because SEC filings "are public records required by the SEC to be filed, the Court may take judicial notice of them"). Accordingly, the Court may consider statements Plaintiff made in its Trademark Office and SEC filings.

# B. The Complaint, Trademark Office records, and SEC filings show that both parties are clinical-stage pharmaceutical companies who do not provide services to others or offer any commercially available products

The Complaint establishes that the parties are clinical-stage pharmaceutical companies that do not provide services for others or sell any commercially available goods. For example, the Complaint states that Plaintiff has one "lead product candidate" that is "currently in Phase III clinical development." (Complaint (Ex. 1),  $\P$  1.) The Complaint alleges that the parties' goods "will be sold" and "will be marketed" at some unspecified time in the future. (Complaint (Ex. 1),  $\P$  18 (emphases added).) The Complaint does not allege that Plaintiff or Defendant has ever provided research services for the benefit of others, or sold any commercially available goods to others.

Excerpts from the Trademark Office records for Plaintiff's federal service mark registration confirm that Plaintiff does not provide any services to others.

Plaintiff describes itself as a "clinical-stage biopharmaceutical company[.]" (Sauter Decl., Ex. 2, p. 11, Ex. 3, p. 8.) Plaintiff also states that its "objective is to develop first-in-class, prescription products ... ." (Id. Ex. 3, p. 8 (emphases added).) Plaintiff states that it "develop[s] prescription therapeutics[,]" (id. Ex. 4, p. 6), and is "focused on the discovery, development and commercialization of novel prescription products for the aesthetic medicine market[,]" (id., Ex. 2, p. 17, Ex. 3, p. 8). Plaintiff never suggests that it has sold any commercially available products or provided any services for others. (See id. at Exs. 2-4.) Plaintiff also confirms that its product candidate, ATX-101, is not commercially available because it is still in clinical trials. (Id. at Ex. 2, p. 11, Ex. 3, p. 8.)

Plaintiff's regulatory filings similarly show that Plaintiff has not provided services to others. Plaintiff's 2012 SEC 10-K Annual Report describes the company as a "clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel prescription products for the aesthetic medicine market." (Sauter Decl., Ex. 5, p.1 (emphasis added).) Plaintiff's Annual Report elaborates that its objective "is to develop first-in-class, prescription products" and that it has one "product candidate, ATX-101", that is still in Phase III clinical development. (*Id.*)

Thus, the record available on this Motion establishes two critical facts: (1) neither party has any commercially available products or services; and (2) Plaintiff performs research services only for its own benefit and to develop its own products.

# C. Plaintiff has alleged facts that establish there is no likelihood of confusion

Plaintiff bases its causes of action on allegations of likelihood of consumer confusion in the marketplace. (*See* Complaint (Ex. 1), ¶¶ 27, 33, 38, 41 (alleging likelihood of confusion)); *see also GoTo.com, Inc. v. Walt Disney Co.*, 202 F. 3d 1199 (9th Cir. 2000) (likelihood of confusion is the central element of trademark

infringement). However, Plaintiff's Complaint fails to allege facts that could plausibly support a finding of a likelihood of confusion. To the contrary, the Complaint alleges facts that establish there is no possibility, let alone a likelihood, of confusion. Accordingly, the Court should dismiss Plaintiff's claims.

As discussed above, Plaintiff alleges that it is still in the "clinical development" phase for its "lead product candidate" for an injectable drug. (Complaint (Ex. 1),  $\P$  1.) Plaintiff similarly alleges that Defendant "is also in the process of developing an injectable drug" that is "currently in Phase II clinical development" for use in humans. (*Id.*) These allegations establish that the parties do not have any commercially available products or services. Plaintiff further alleges that, "[t]he parties' respective goods ... *will be* sold" and "*will be* marketed" at some unspecified point in the future. (*Id.*,  $\P$  18 (emphases added).) These allegations confirm that there can be no confusion, and any potential future competition or confusion between the parties' products is entirely speculative at this point because neither has an FDA approved product.

There can be no likelihood of confusion where there are no competing commercially available goods and/or services that could be confused in a marketplace. It has been the law in the Ninth Circuit for more than half a century that, "[p]erhaps the most important element of unfair trade is that there be *competition in the sale of like merchandise* and that there is, or is likelihood of, confusion as to which *competitive article* is being purchased." *Mister Donut of Am., Inc. v. Mr. Donut, Inc.*, 418 F.2d 838, 843 (9th Cir. 1969) (emphases added). Thus, where, like here, there is absolutely no competition between the parties, there can be no likelihood of confusion.

Nor can there be any likelihood of confusion where there is no consuming public that could be confused. The Ninth Circuit has similarly observed that, "[t]he test for likelihood of confusion is whether a reasonably prudent *consumer* in the marketplace is likely to be confused as to the origin of the good or service

bearing one of the marks." *Entrepeneur Media, Inc. v. Smith*, 279 F.3d 1135, 1140 (9th Cir. 2002) (emphasis added). Thus, when there are no purchasers of goods and/or services in any marketplace, there can be no likelihood of confusion.

Plaintiff's concern seems to be related to its allegation that "sophisticated individuals in the field of pharmaceuticals and in the press" have confused the mechanism of action of the parties' respective clinical-stage products. (*See* Complaint (Ex. 1), ¶ 19.) Scientific confusion about the way the parties' potential products function in the body does not give rise to any cause of action and does not establish a likelihood of confusion in a trademark sense.

The only type of confusion that is relevant to trademark law is whether the consuming public is likely to be confused as to the source of the goods or services. *Rearden LLC v. Rearden Commerce, Inc.*, 683 F.3d 1190, 1214 (9th Cir. 2012). This is because "trademark infringement protects only against mistaken purchasing decisions and not against confusion generally." *Id.* (internal quotation omitted). As Judge Stotler has observed, "[s]ome people are always confused." *Playboy Enters., Inc. v. Netscape Commc'ns Corp.*, 55 F. Supp. 2d 1070, 1083 (C.D. Cal. 1999). "Accordingly, to impose liability, the plaintiff must show confusion of *a significant number of prospective purchasers*." *Id.* (emphasis added).

In the absence of any commercially available goods or services, there are no prospective purchasers who could be confused. Where there is no relevant consuming public that *could be* confused, there is certainly no consuming public that is *likely* to be confused. Accordingly, Plaintiff has not alleged any facts that plausibly suggest a likelihood of confusion by the relevant consuming public, and the Court should dismiss the Complaint.

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## D. Plaintiff has not acquired any service mark rights because its research services are solely performed for its own benefit

The Complaint should also be dismissed for the independent reason that Plaintiff has alleged facts that establish Plaintiff lacks any enforceable trademark rights in its service marks. In order to acquire trademark rights in a service mark, the mark must be used for the benefit *of others*. *In re Canadian Pacific Ltd.*, 754 F.2d 992, 994 (Fed. Cir. 1985). If the use is solely for the benefit of the alleged owner of the mark, the use does not give rise to trademark rights. *Id*.

Use of the mark in connection with performing services for the benefit of others is a necessary predicate both to establishing common-law trademark rights, see Chance v. Pac-Tel Teletrac, Inc., 242 F.3d 1151, 1156 (9th Cir. 2001), and to receiving a federal registration for a service mark, see Aycock Eng'g, Inc. v. Airflite, Inc., 560 F.3d 1350, 1357-58 (Fed. Cir. 2009). "At the very least, in order for an applicant to meet the use requirement, there must be an open and notorious public offering of the services to those for whom the services are intended." Id. at 1358. Advertising or publicizing a service that the applicant intends to perform in the future will not support registration. Id. Adopting a mark and preparing to begin its use are similarly insufficient to claim ownership of a mark or apply for its registration. Id.

Plaintiff uses its mark as the name of its company. (Sauter Decl., Ex. 2.) However, Plaintiff does not perform or offer to perform any research services for others. Because Plaintiff has not performed services for the benefit of others, it has no enforceable service mark rights, and its service mark registrations for research services are void *ab initio*. *Id.* at 1357. As discussed above, the Complaint, Plaintiff's representations to the United States Patent and Trademark Office in connection with obtaining the asserted service mark registrations, and Plaintiff's public SEC filings, all show that Plaintiff has not used its asserted marks in connection with any services for the benefit of others. Plaintiff's research services

are performed solely for its own benefit. Thus, Plaintiff's conclusory allegation that it has enforceable service mark rights is contradicted by other allegations in the Complaint as well as by matters of public record.

If the allegations in the Complaint had not established Plaintiff's lack of bona fide use for others, and if the lack of use for others were not a matter of public record, Plaintiff might have been able to rely on the mere existence of its federal registrations as prima facie evidence of actual service mark rights. *See* 15 U.S.C. §§ 1057(b); 1115(a); *Brookfield Commc'ns, Inc. v. West Coast Entm't Corp.*, 174 F.3d 1036, 1047 (9th Cir. 1999). However, where, as here, the allegations in the Complaint and available public records establish the mark was not used in connection with services performed for others, the registration is void *ab initio.* Aycock Engineering, 560 F.3d at 1357. Accordingly, the Court need not, and should not, accept Plaintiff's allegations of enforceable service mark rights as true. See Daniels-Hall, 629 F.3d at 998.

Plaintiff has failed to allege facts sufficient to establish a plausible claim that it has enforceable trademark rights in its alleged service marks. This is yet another reason the Court should dismiss Plaintiff's claims.

## E. <u>As a practical matter, Plaintiff's claims are premature because the Court could not even conduct the likelihood of confusion analysis</u>

Plaintiff's Complaint also appears to ask the Court to speculate regarding whether there will be any likelihood of confusion among relevant consumers regarding the parties' respective lead product candidates if both products reach the market. This issue is both premature and unanswerable. Many of the factors the Court would apply in determining whether there is a likelihood of confusion simply cannot be applied where there are no commercially available goods or services. *See AMF Inc. v. Sleekcraft Boats*, 599 F.2d 341, 348-355 (9th Cir. 1979) (discussing eight factors to be applied).

For example, one of the eight factors this Court would consider in assessing likelihood of confusion is the proximity of the goods and/or services in the marketplace. *Id.* The Court cannot analyze the proximity of unavailable goods and/or services in a non-existent marketplace. Another factor the Court would consider is the similarity of the marks. *Id.* The Court cannot analyze this factor without knowing the names of the products. The parties' product candidates are currently known by clinical research identifiers ATX-101 and LIPO-202. Before they are launched commercially, they will be given product names and trade dress that could eliminate any possibility of confusion. It would be pointless to speculate as to what the product names and packaging might be, or how those unknown details might impact consumers in a hypothetical future market.

In assessing likelihood of confusion, the Court may also consider evidence of actual confusion in the marketplace. *Id.* However, the Court would not be able to analyze whether there is any actual confusion in the relevant marketplace until there is a commercial market for the products. Another factor is the marketing channels used. *Id.* Again, the Court could not evaluate this factor unless and until there are commercially available products and actual marketing channels being used. Another factor is the degree of care likely to be exercised by a purchaser of the goods and/or services. *Id.* It would be difficult, if not impossible, to meaningfully assess the likely degree of care exercised by potential consumers without knowing who those consumers are going to be.

At this point, any attempt to guess what the parties' products might be called, how they might be marketed, to whom they will be marketed, or how they might be positioned in their respective markets, would be pure speculation. The Court would not be able to offer anything more than an unconstitutional advisory opinion as to how likely confusion might be under various potential scenarios. A court simply cannot assess the likelihood of confusion where, as here, no goods and/or services have been sold by either party.

IV. CONCLUSION Plaintiff's Complaint does not suffice under Iqbal and Twombly because it does not allege any facts that, if true, would plausibly give rise to enforceable trademark rights or a likelihood of confusion by consumers. Plaintiff's conclusory allegations are contradicted by the facts in the Complaint and by available government records. Accordingly, the Court should dismiss the Complaint. Respectfully submitted, KNOBBE, MARTENS, OLSON & BEAR, LLP Dated: November 25, 2013 By: /s/ Benjamin A. Katzenellenbogen Benjamin A. Katzenellenbogen Emily K. Sauter Attorneys for Defendant LITHERA, INC. [16513240] 16733708\_3